



First do no harm

To the Editor: Should an organisation representing a profession with a millennia-old tradition of *Primum non nocere* (First do no harm) place itself in an alliance that makes it difficult to speak out against actions which break one of the basic tenets of medical and human ethics?

I sent the following by e-mail to SAMA on 19 June, while the public servants' strike was on, in response to Med-e-Mail Vol. 4 No. 17 dated 8 June 2007, and to several of the e-mail addresses supplied, and have received no response from SAMA. But even though the strike is over and emotions involved have faded somewhat, the issues remain.

'While recognising that nurses should be better paid and the legitimate role of the labour movement in society, what has been happening in this strike also at Tygerberg has left me feeling very uncomfortable.

'The statement of the SA Democratic Nurses Union's provincial secretary [sic] Fanie Mashile, quoted in the *Sunday Independent* of 10 June 2007, highlights my concerns very clearly:

"It is sad that patients have to be sacrificed for the employer to realize that we are serious. People have to understand that that there is no struggle without casualties. Unfortunately the casualties are innocent patients who die because the employer does not want to give us what we are worth as civil servants," he said. He offered his condolences to families who had lost loved ones during the strike. "Our hearts are with the families who are losing loved ones in hospital because workers are on strike, but we cannot do otherwise until the employer gives us what we want."

'Is this the statement of an official out of line with strike leaders' thinking? Mashile's statements seem to me to be the result of serious group discussion. At least he is willing to publicly and realistically face the implications of his leadership. Less blatant statements from the other strike organisers are in a similar vein. The violence and incitement were obviously organised – despite utterances to the contrary such as those of a union official also from DENOSA, talking on SAFM about 7.10 on Monday morning 11th June – "... isolated incidents as a result of the provocative actions by the police ..."

'Has SAMA clearly distanced itself from such statements and from organised disruptive behaviour of striking workers? I might have missed it.

'The communication from SAMA in the form of the Med-e-mail of 8 June (in which the Industrial Relations Unit of SAMA outlined the legal position of doctors) seems to me to demonstrate an inability or unwillingness to clearly face the implications of group-think in trade union action, and leaves me rather nonplussed.

'The only reference to patient health and safety is advice for doctors to keep within their normal scope of practice, with the exception of a life-threatening situation.

'I am not sure that I want to continue to be a member of an association which does not take a stand in the face of actions harmful to patients and other health workers. If SAMA is not free to speak out, should it be part of the COSATU alliance?'

Medigram Vol. 15 No. 11 of 29 June 2007 blames the absence of a minimum service agreement for the 'reported cases of friction' on the health sector – again trying to shift responsibility for wrongdoing to a third party, instead of distancing itself from the actions by participants in the strike, which were blatantly unethical.

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Quantifying antiretroviral risk in pregnancy

To the Editor: Efavirenz, a pregnancy risk category D antiretroviral (ARV) drug, has been associated with the development of anencephaly, myelomeningocele and microphthalmia in animal models. Four retrospective cases of neural tube defects have been reported in human fetuses,¹ but limited obstetric and neonatal outcome data on the risk associated with efavirenz are available. The US prospective pregnancy registry has detected no increase in risk of birth defects following exposure to efavirenz in the first trimester,^{2,3} and many clinicians believe that risks to the fetus may have been exaggerated. These conflicting opinions led us to evaluate the obstetric and neonatal outcomes of pregnant patients on efavirenz at our ARV clinic since 2002.

A total of 37 out of 50 women had analysable data. Their average age was 32 years, WHO stage 3, weight 66 kg, baseline CD4 count 136 cells/ μ l, and viral load 352 919 copies/ml. The CD4 count improved on highly active antiretroviral therapy (HAART), with the average count of 245 cells/ μ l at pregnancy detection improving to 296 cells/ μ l at delivery. The average viral load also improved, decreasing from an average of 62 630 copies/ml at pregnancy detection to 8 810 copies/ml at delivery.

Obstetric outcomes. Of the women 15% decided to have a termination of pregnancy, 29% had a caesarean section, which compares favourably with the Gauteng provincial caesarean section rate of 17.7%,⁴ and 34% delivered at a level 2 hospital (Kalafong Hospital Neonatal Statistics, January - December 2006 – unpublished). There were no reported cases of premature rupture of membranes or chorio-amnionitis.



Neonatal outcomes. The average birth weight was 2 260 g (range 2 320 - 3 000 g). Eleven per cent of women had a low-birth-weight baby, comparing well with the Gauteng provincial rate of 18%⁴ and level 2 hospital rate of 19.2% (Kalafong Hospital Neonatal Statistics, January - December 2006 - unpublished). There was no significant association between birth of a low-birth-weight baby and the age, weight, WHO stage or parity of the mother, or her CD4 count and viral load at any stage before or during her pregnancy. There was 1 neonatal death, due to respiratory distress. Significantly, there were no reported cases of morphological abnormalities, neural tube defects, or overt developmental delay. Only 12 mothers brought their babies for their HIV polymerase chain reaction test at 6 weeks; 1 baby tested positive for HIV (8%).

Conclusion. No increased risk of adverse obstetric and neonatal outcomes was demonstrated in a small number of HIV-positive women who fell pregnant while taking efavirenz. Limitations of the study are the small number of cases, the retrospective nature of the analysis, and the limited number of first-trimester exposures. The study highlights the need for active pregnancy surveillance of this new class of medication and the urgent need to monitor neonates exposed to ARVs. We therefore propose that a formal, prospective, multi-site pregnancy registry be established, and invite interested parties to contact me for information on participation.

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Retained swab at Frere Hospital

To the Editor: The 'After Eight Debate' on SAFM on Friday 13 July 2007 concerned the *Eastern Cape Herald's* report on the unacceptable neonatal mortality rate at Frere Hospital. Most upsetting for the callers and the host was the reported incident of a retained swab after a caesarean section. The responses were often emotional, calling for immediate investigation and prosecution by the HPCSA of medical and nursing staff guilty of negligence. Unfortunately, retained swabs and instruments are an ever-present threat, especially in emergency surgery performed after normal hours in adverse circumstances.¹ Authorities participating in the show seemed eager to play up

the issue of negligence – which is the wrong response to the situation and does not take into account modern theories of human error.

Error is a human feature, and no human being has not at some point lost house keys, forgotten to turn off the stove or run out of petrol.² Such errors are minor and irritating; however, when made by someone in charge of an aeroplane or a nuclear power station, the consequences could be most significant. Human error accounts for a great deal of morbidity and mortality in health care. The Institute of Medicine report, entitled *To Err is Human*, alleged that human errors were responsible for 44 000 - 98 000 deaths annually in the USA.³ It called for a more comprehensive understanding of the mechanism behind these errors so as to facilitate the development of preventive systems. The report extrapolated on the work of psychologists who have studied human error in various settings.^{2,4,5} Two approaches to human error are the person approach and the systems approach.

The person approach blames the individual – which is emotionally more satisfying. Traditionally, medical error has been dealt with in-house by the so-called 'blame and train' approach based on a retrospective morbidity and mortality meeting. If done honestly and constructively, important messages can be learnt. However, this knowledge is not institutionalised and tends to remain with the individual. The next generation of staff may have to re-learn the lesson the hard way. In the broader community, medical error has been dealt with by medico-legal processes, again focusing on the individual, which limits closer scrutiny of systematic failures which, although difficult to detect, are significant sources of error. Adverse events are seldom the result of single acts of 'human bloody-mindedness', and health care workers function in a complex system where technology and humans interact. The 'human factors approach' looks beyond the individual and focuses on pre-existing conditions that create environments which foster the potential for error. Latent system errors – such as inadequate staffing, long working hours and inadequate supervision – underlie the errors made by staff who deliver health care. We cannot change the human condition, but we can change systems so as to prevent recognised error patterns from occurring. Mechanical approaches to this end include physical lock-outs, defence-in-depth strategy, mandatory early warning systems, and enforced clinical pathways or algorithms. It is essential that latent failures in systems are addressed as a priority, including the problems germane to most of our state health institutions, namely understaffing, ageing infrastructure, overcrowding, inadequate remuneration and lack of supervision.

Prosecuting the staff involved in the retained swab incident won't ensure that it will not happen again and may simply allow management to wriggle off the hook. We do not need to root out a few bad apples, but rather to develop a